

REMARKS

This amendment is filed along with a Request for Continued Examination, as the amendment to the claims is expected to require further consideration and/or search.

The application is amended in a manner to place it in condition for allowance.

Claims 32, 46 and 59 are amended to recite the particular polyurethane, i.e., one obtained by polyaddition reactions of diols and diisocyanates.

Support for the amended claims may be found, for example, at page 8, lines 1-6, page 9, and the Examples of the specification.

Claims 32, 36-46, 50-57, and 59-65 remain pending.

Claims 32-34, 37-42, 44, 46-48, 51-56, and 59-63 were rejected under 35 USC §102(b) as anticipated by MARINOVIC EP 0 280 451(MARINOVIC). This rejection is respectfully traversed for the reasons that follow.

The position of the Official Action is that the polyether urethane urea polymer of MARINOVIC falls with the scope of the claimed polyurethane, that the method of how the polymer precipitates is not considered for the claimed invention, and that MARINOVIC does not disclose that the composition adhere to the blood vessel walls.

However, MARINOVIC cannot anticipate, or even render obvious, the claimed invention for at least three reasons:

I. The claimed polyurethane.

The position of the Official Action is that "any polymer consisting of a chain or organic units joined by urethane links."

However, the very name of the polymer disclosed by MARINOVIC suggests a different polymer than that of the claimed polyurethane.

Urethane groups are responsible for the formation of a polyurethane, and, consequently, they are the dominant functional groups of the formed polymers. If there are other dominant functional groups in the polymer, then it should be declared in the name of the polymer, in line with the general rule of the polymer chemistry.

If there are different monomers in the polymer and the polymer is built up by the formation of different linkage groups (e.g. urea groups like in MARINOVIC) then, very obviously, a different type polymer is formed and this important structural difference should be demonstrated in the name of polymer (again, in line with the general rule of the polymer chemistry). This is why the polymer of MARINOVIC is named as polyetherurethane urea. The polymer formed in MARINOVIC contains urethane groups only in the closing groups of the polyether type monomers, so it is only a minor (tertiary, after the polyether and urea groups) component of the formed polymer.

Indeed, polyurethane is defined in the RÖMPPS CHEMIE-LEXIKON (7th Edition, Kosmos-Verlag, Stuttgart, title: Polyurethanes) that the polyurethanes "are linear macromolecules formed by the polyaddition reaction of diisocyanates and diols and they are polymerized in space (cured) if triisocyanates and glycols with branched structure take place in the reaction".

Moreover, the formation of the polymer of MARINOVIC suggests that the polymer is different from the claimed polymer.

The independent claims 32, 46, and 59 are directed to a polyurethane solution, where the polyurethane is obtained by polyaddition reactions of diols and diisocyanates.

MARINOVIC, however, forms a polyetherurethane urea polymer from a pre-polymer. See, e.g., the reaction described on page 4 of MARINOVIC. The polyetherdiurethane diisocyanate prepolymer is reacted with a diamine-type of "chain extender" [-NHCONHCH₂CH₂NH-] so that the polyether type core is linked together with urea-type groups to form the final "polyetherurethane urea" polymer: OCN-Z-NHCOO-(polyether)-OCONH-Z-NCO.

MARINOVIC further discloses, "In principle, all free NCO groups are converted to urea (or related groups depending upon the exact nature of the chain extending compound) in the formation and hardening of the space filling adhesive." See, e.g. page 6, lines 9-10. Thus, the resulting polymer comprises many

ether polymers and two urethane terminal groups, i.e., the polymer is a diisocyanate-type compound having a polyether core.

Thus, MARINOVIC fails to disclose the claimed polyurethane.

Indeed, taken as a whole, MARINOVIC, teaches away from the claimed invention, as MARINOVIC avoids the use of the name "polyurethane" for the polymer, and the fact that there are urethane groups in the structure.

II. The method of precipitating the claimed polyurethane.

The position of the Official Action is that MARINOVIC teaches the pre-polymer in conjunction with an aqueous solution of chain extender are combined in a suitable vessel, stirred and taken up via a syringe, and the polymer solution solidifies once administered as a the tissue adhesive.

However, this description is different from the claimed invention in that (1) the polymer is not dissolved in a solvent and (2) the polymer is not solidified by removing the solvent.

MARINOVIC forms a solid polymer *in situ*, i.e., as a result, from the reaction between a liquid pre-polymer and a chain extender. See, e.g., page 5, lines 30-47, and Examples B1-B9. The very focus of MARINOVIC is to prepare a hardened space filling adhesive (see the top of page 6 and claim 1).

Accordingly, neither the liquid pre-polymer nor the polymer of MARINOVIC is described as capable of being dissolved in a solvent as recited in claims 32 and 46, and solidified upon removal of the solvent as recited in claim 59. Moreover, as the polymer of MARINOVIC is formed by cross-linking or hardening the pre-polymer, it is not disclosed as being dissolved in solvent and solidified upon removal of the solvent.

The differences in these characteristics between the claimed polymer and the polymer of MARINOVIC are even more apparent by the fact that MARINOVIC avoids the polar aprotic solvents, e.g., DMSO, for preparing the liquid prepolymers. These very same solvents, e.g., as recited in claims 36, 50, and 61, are used to dissolve the claimed polymers.

Thus, MARINOVIC neither discloses nor suggests the claimed polymer characteristics, or method of precipitating the polymer as stated in the Official Action.

III. The composition does not stick to blood vessel walls.

The position of the Official Action is that MARINOVIC "does not state that the compositions adhere to the blood vessel walls".

However, MARINOVIC identifies the polymer as a tissue adhesive.

Independent claims 32, 46, and 59 recite that the composition does not stick to the blood vessel walls. These claims also recite that the compositions "consist essentially of" a polymer and solvent or solvent mixture. Thus, an "adhesive" affect the novel characteristics of the claimed invention, i.e., causing the composition to stick to the blood vessel walls.

Thus, MARINOVIC fails to disclose or suggest the polymer would not stick to blood vessel walls.

In view of the above, MARINOVIC cannot anticipate independent claims 32, 46, and 59, and dependent claims 36-45, 50-57, and 60-65, nor render obvious these claims.

Therefore, withdrawal of the rejection is respectfully requested.

Claims 32-37, 39, 43-51, 53, 56-57, 59 and 61-65 were rejected under 35 USC §102(e) as being anticipated by PORTER US 20002/0165583 (PORTER). This rejection is respectfully traversed for the reasons that follow.

The position of the Official Action is that the separate disclosure of polyurethanes and polymers dissolved in a solvent is sufficient to describe the claimed polyurethane solution.

However, PORTER cannot anticipate the claimed invention for at least the two reasons below:

I. The claimed polyurethane solution.

PORTER fails to specifically disclose a polyurethane polymer dissolved in a solvent as recited in claims 32 and 46, or capable of dissolution in a solvent and capable of solidifying upon separation from the solvent as recited in claim 59.

PORTER discloses two main concepts, e.g., (i) a method for *in situ* polymerization at a vascular site and (ii) an apparatus for delivering the liquid embolic solution to the vascular site. When polymer solutions are mentioned, they are "compositions known in the art" (See [0087], [0021] to [0025], [0033], and claims 36 to 42), but those compositions listed by PORTER do not include polyurethane, e.g., in [0005].

PORTER, instead, only refers to polyurethane in terms of its preparation from the prepolymer components (e.g., [0050], [0059], and [0066]), and the cross-linking is emphasized ([0059], [0066]) which makes dissolving the polymer impossible. These polyurethanes are not soluble (see e.g. the polyurethane foams applied for the fixation of doors, windows etc., other solid polyurethane objects).

Indeed, as discussed in the present specification at page 6, the general insolubility of polyurethanes is recognized in US 5,702,361 (even if they are prepared from liquid prepolymers) and in US 6,342,202, where the solubility of polymers in DMSO is discussed, the polyurethane is given as non-soluble material, see Table 1.

At the end of [0005], PORTER discloses that these materials often require the use of elaborate delivery systems. In [0006] it is discussed that sometimes carrier solution can be applied (as a delivery system) from which "a preformed polymer precipitates in situ". However, PORTER fails to disclose the use of solutions of preformed polyurethane.

In the claimed invention, however, a polyurethane polymer is dissolved in a solution. Accordingly, the claimed invention is distinguished from the formation of polyurethane from liquid prepolymers, as there is a state when the mixture is liquid, but there are polyurethane polymer chains in the mixture. This liquid mixture is not a solution of a preformed polymer, only a intermediary reaction mixture where the polymerization is running, resulting in a solid product.

However, when polymer solutions are discussed in PORTER (see, e.g., [0087]), then it concentrates on speeding up the reaction, i.e. speeding up the removal of the solvent from the polymer solution; no specific polymer is mentioned.

Thus, PORTER fails to disclose polyurethane solution as claimed.

II. The claimed composition does not stick to blood vessel walls.

PORTER teaches that "anchoring" of the precipitating polymer is necessary (see claim 36, which is the main claim for the composition containing liquid embolic solution and parts [0006] and [0022]).

Thus, PORTER cannot disclose a composition does not stick to blood vessel walls.

Therefore, PORTER cannot anticipate claims 32, 46, and 59, and dependent claims 36-45, 50-57, and 60-65, and withdrawal of the rejection is respectfully requested.

Claims 32, 36-46, 50-57, 59 and 61-65 were rejected under 35 USC §103(a) as being unpatentable over PORTER. This rejection is respectfully traversed for the reasons stated below.

As discussed above relative to the anticipation rejection, PORTER discusses polyurethanes and polymer solutions, but fails to suggest a polyurethane solution. Indeed, PORTER teaches away from providing a polyurethane solution, where the polyurethane solidifies in the absence of the solvent, as the polymer solutions include a cross-linked polymer. A cross-linked polymer would not be capable of being dissolved in a solvent and re-solidifying in the absence of the solvent.

Moreover, the fact that PORTER requires the anchoring of the polymer to blood vessel (see, e.g., [0006] and [0022],

which teaches away from a composition that does not stick to the blood vessel walls.

Therefore, PORTER cannot render obvious the claimed invention.

In view of the amendment to the claims and the foregoing remarks, the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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